DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Public Health and Science

Office for Human Research Protections
1101 Wootton Parkway Suite200
Rockville, MD 20852

Telephone: 301-496-7005
http://ohrp.osophs.dhhs-gov/polasur.htm

FROM: Division of Policy and Assurance
Office for Human Research Protections

RE: OHRP Approval of Federal-Wide Assurance (FWA)

The Office for Human Research Protections (OHRP) has approved the enclosed Federal-Wide Assurance (FWA) recently submitted by your institution. The FWA is approved for a three-year period and should be renewed prior to its expiration. Any update in the FWA should be submitted to OHRP by completing a new FWA form.

The **FWA identification number** is important and will be required in certain forms (e.g., PHS-2590) and for certification of IRB review to funding authorities. Under this Assurance, the designated Institutional Review Board(s) JRBs) is/are recognized as the responsible IRB(s) for fulfilling, in part, the requirements of the Federal regulations at 45 CFR 46.

No human subject research for which this FWA applies may be initiated at your institution prior to approval by the OHRP-registered IRB(s) designated in this FWA. The principal investigator and the awardee institution are responsible for ensuring that every collaborating institution engaged in Federally conducted or supported research has appropriately assured compliance with 45 CFR 46 and complied with the IRB requirements prior to its involvement of human subjects. Failure to comply may result in fiscal sanctions by the supporting agency.

This Assurance defines the relationship of your institution with the supporting Federal Department or Agency. It sets out your responsibilities and the procedures that will be used by your institution to protect human research subjects. Among the most important elements of the assurance to comply are the prompt reporting requirements to the relevant Department of Agency head, any applicable regulatory body, as well as this office, and your agreement to ensure that the appropriate training and educational requirements as described in the terms of the FWA are fulfilled. **Your institution should consult with the supporting department or agency with regards to any additional requirements and/or guidance for human subjects research.**

The Federal regulations, policy, and guidance on the conduct of human subject research may be found at the OHFLP website at http://ohrp.osophs.dhhs.gov.

Do not hesitate to contact OHRP should you have any questions.

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
3710 Southwest U.S. Veterans Hospital Road
Portland OR 97207

02 JAN 24

In Reply Refer To: X Update

DIRECTOR _ New Filing

Department of Health and Human Services
Federalwide Assurance of Protection for Human Subjects

(1)
Portland VA Medical Center
Portland, OR 97201 USA
HHS Institution Profile File (IPF) code, if known:
Federal Entity Identity Identification Number (EIN), if known: 931127631

assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the **The Belmont Report.**

(2)This institution assures that all of its activities related to Federally- supported human subject research will comply with the following procedural standards: **45 CFR 46 as Stipulated in the Terms of Assurance for Protection of Human Subjects Within the United States.**

This institution elects to assure compliance with the Terms of Assurance for all of its human subject research, regardless of funding source.

(3) Institutional Components

List below all components of the institution that may operate under a different name [e.g., All Saints Medical Center is comprised of All Saints Hospital, St. Mary's Children's Hospital, St. Mathias Psychiatric Hospital, and St. Paul's Rehabilitation Center]. Also list any alternate names under which the institution may operate. The institution should have available, for review upon OHRP request, a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the IRB, IRB support staff, and investigators in the various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the named institution and all components listed here. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

X Please check here if there are no such components or alternate names.

(4) Operations, Procedures, and Oversight Mechanisms (a, b, c, e = optional)

(a) Institutional procedures for protecting human subjects were last updated on: **June 2001**

(b) These procedures include formal mechanisms for monitoring compliance with human subject protection requirements. X Yes __No

(c) The institution has established continuing programs to educate IRB members, IRB staff, and research investigators about human subject protection requirements. X Yes __No

(d) For Domestic Institutions, the Signatory Official, Human Protections Administrator, and IRB Chairpersons of all designated IRBs have completed the relevant OHRP modules(s), and other staff are appropriately trained. For International Institutions, relevant personnel -are required to complete appropriate comparable training. X Yes __No

(e) Number of full time positions devoted solely to human subject education activities: **None**

(f) If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number: M-1359 ~~(this submission is intended to update FWA00000517)~~ PC No FWA

(5) Designation of Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs)

This institution designates the following IRB(s) for review of research on a regular basis* under this Assurance *(if the IRB is not previously registered with HHS or has not provided a membership roster to HHS, please attach the necessary materials available elsewhere on this website).*

* Institutions may, on an occasional or ad hoc basis, choose to rely on an IRB operating under another Institution's Assurance. Such occasional reliance must be documented in writing and provided to OHRP upon request, but need not - be listed below. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the institutions may develop their own agreement.

HHS IRB Registration Number	Name of IRB As Registered with HHS	Name and Signature of IRB Chairperson or IRB Organization Head Authorizing Designation of the IRB Under This Assurance
PC HIRB 00001976	Portland VAMC IRB #1 PC	Dennis Mazur, MD, PhD 06/25/01 Dennis J. Mazur, M.D., Ph.D.

(6) Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person -- cannot be IRB Chairperson):

Sola Whitehead
Coordinator, Portland VAMC Institutional Review Board
Portland VA Medical Center
3710 SW US Veterans Hospital Road (Mailcode: R&D)
Portland, OR 97201
(503) 402-2885
(503) 273-5351 (FAX)
sola.whitehead@med.va.gov

Human subject protection training last taken on: OHRP Training Modules - January 2001,
PRIM&R/ARENA Training - May 2000

(7) Signatory Official (i.e., Official Legally Authorized to Represent the Institution -- cannot be IRB Chairperson or IRB member):

Acting officially and in an authorized capacity on behalf of this institution, I assure protections for human subjects as specified above. The IRBs above are designated to provide oversight for research under this Assurance. These IRBs will comply with the terms of the Assurance and possess appropriate knowledge of the local context in which this institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I have personally satisfied the education requirements referenced in the Terms of Assurance and will require that all other relevant personnel also do so. I will further require that all such personnel receive appropriate additional initial and continuing education about human subject protection requirements. *(Note: False statements could be cause for invalidating this Assurance and may lead to administrative or legal action.)*

I understand that all collaborating institutions engaged in Federally-supported human subject research must submit their own Assurance.

Signature *James Tuchschmidt* Date: June 28 2001

James Tuchschmidt, M.D., M.M.
Chief Executive Officer
Portland VA Medical Center
3710 SW US Veterans Hospital Road (Mailcode: P- I -CEO)
Portland, OR 97201
(503) 273-5125
(503) 273-5351 (FAX)
James.Tuchschmidt@med.va.gov

Human subject protection training last taken on: OHRP Training Module – ~~May~~ *June* 2001

Department of Health and Human Services
Federalwide Assurance of Protection for Human Subjects

ADDITIONAL PAGE REQUIRED FOR DEPARTMENT OF VETERANS AFFAIRS VETERANS HEALTH ADMINISTRATION FACILITIES

Portland VA Medical Center
assures that all of its pertinent activities related to human subject research will comply with all requirements of Department of Veterans Affairs regulations at Title 38 Code of Federal Regulations Part 16 (38 CFR 16), and all other pertinent Department of Veterans Affairs policies and procedures, including policies and procedures of the Office of Research Compliance and Assurance (ORCA) and the Office of Research & Development (ORD), issued in Manuals, Handbooks and other relevant authorized Directives.

(7a.) Official Legally Authorized to Represent the Institution:

Signature *James Tuchschmidt* Date: *JUN 28 2001*

James Tuchschmidt, M.D., M.M.
Portland VA Medical Center
3 7 10 SW US Veterans Hospital Road (Mailcode: P- I -CEO)
Portland, OR 97201
(503) 273-5125
(503) 273-5351 (FAX)
James.Tuchschmidt@med.va.gov

Human subject protection training last taken on: OHRP Training Module - May 2001

(7b.) Official Legally Authorized to Concur in the Institution's Approval (VHA VISN Director):

Signature *Wm. Ted Galey, M.D.* Date: *7/6/01*

Wm. Ted Galey, M.D.
Director, VISN # 20
1601 E. 4th Plain Blvd. (10N20)
Vancouver, WA 98661
(360) 690-1832
(360) 737-1405 (FAX)
Ted.Galey@med.va.gov

Human subject protection training last taken on: OHRP training module - March 30, 2001

(7c.) Department of Veterans Affairs Approval

(Section Below to be completed by the Office of Research Compliance and Assurance)

This Federal-wide Assurance of Protection for Human Subjects is hereby approved for submission to the Department of Health and Human Services (HHS).

VHA Recommending Official

Signature of VA Recommending Official:

Name: Priscilla A. Craig *Priscilla A. Craig* Date: *12/14/01*

Title: Health Science Specialist Federal Wide Assurances
Office of Research Compliance and Assurance

Signature of VA Approving Official:

Name: John H. Mather M.D. *John H. Mather M.D.* Date: *12/14/01*
Title: Chief Officer,
. Office of Research Compliance and Assurance

Any Additional Comments:

Office of Research Compliance and Assurance (10R)
811 Vermont Avenue, NW, Suite 574
Washington, DC 20420

Phone: (202) 565-8162
FAX: (202) 565-9194

E-mail: Priscilla.craig@hq.med.va.gov

(8) HHS Approval

The Federalwide Assurance of Protection for Human Subjects submitted to HHS by the above institution is hereby approved for the conduct of Federally-supported research.

Signature of HHS Approving Official: *Kamal K. Mittal* Date: *12/26/2001*

Kamal K. Mittal, D.V.M., Ph.D.
Division of Assurances and Quality Improvement
Office for Human Research Protectionsv OPHS9 05, DHH5
The Tower Building, 1101 Wootton Parkwav, Suite 200
Assurance Number: **Rockville, MD 20852**
Phone: (301) 402-5971 Fax: (301) 402-0527
E-Mail: Kmittal@OSOPHS.DHHS.GOV